40. (Amended) A dietary supplement in unit dosage form for delivery of a daily dose of said dietary supplement, which consists essentially of (i) at least 1 gram of GLA for increasing DGLA levels of a user, thereby inhibiting the metabolism of arachidonic acid, (ii) an effective amount of a Δ^5 desaturase inhibitor for inhibiting accumulation of arachidonic acid in the serum of said user and, optionally, (iii) an effective amount of a competitive inhibitor of arachidonic acid metabolism, wherein the supplement provides GLA and the Δ^5 desaturase inhibitor in a ratio of from about 1:1 to about 2:1.

49. (Amended) A dietary fatty acid supplement consisting essentially of purified water, ascorbyl palmitate, sorbic acid, sucrose, glycerin, xanthan gum, concentrated borage oil, concentrated marine oil, flavor and colorant, wherein the supplement provides GLA and the Δ^5 desaturase inhibitor in a ratio of from about 1:1 to about 2:1.

REMARKS

Status of the Claims

The application was filed with claims 1-51. In response to a Restriction Requirement of June 5, 2001, Applicant elected claims 1-46 and 49-51 and requested cancellation of claims 47 and 48 in a preliminary amendment. The Examiner has not acknowledged this amendment, therefore, Applicant has again requested cancellation of claims 47 and 48 as drawn to a non-elected invention. Claims 1, 2, 19, 20, 25, 40 and 49 have been amended. Claims 1-46 and 49-51 are currently in the case.

Claim 26 further limits claim 25 and is thus a properly dependent claim.

The Action objects to claim 26 as an improper dependent claim for failing to further limit claim 25, stating that it is an inherent property of the composition that the fatty acids are isolated from a transgenic cell engineered to produce at least one fatty acid. This objection appears to be

based on the position that all the claimed unsaturated fatty acids are inherently isolated from a transgenic cell engineered to produce the unsaturated fatty acid, a position that is clearly erroneous. The Examiner's attention is drawn to the Specification at page 8, lines 12-14 wherein is stated that the unsaturated fatty acids may be isolated from natural sources such as plants or animal tissues, or they may be isolated from transgenic cells engineered to produce the unsaturated fatty acid. The use of unsaturated fatty acids that are isolated from natural sources, such as plants would infringe claim 25, but would not infringe claim 26. The claim is thus further limiting and complies with 35 USC 112 4th paragraph and 37 CFR 1.75(c). Applicant respectfully requests that this objection be withdrawn.

The Action also rejects claims 8, 29, and 40-44 as indefinite. Applicant respectfully traverses. The use of the term "further defined as comprising" does not render claims 8 or 29 indefinite or ambiguous in any way, nor would one of skill in the art have any trouble understanding that the ingredients listed in those claims are part of the compositions. It is the function of all dependent claims to further define or to further limit the independent claims from which they depend and thus the language of the transition phrase is proper and clear. Applicant respectfully requests that this rejection be withdrawn.

Regarding claims 40-44, Applicant submits that GLA, DGLA, SA, and EPA are not trade names or trademarks, but rather are art-accepted abbreviations for the claimed unsaturated fatty acids. These abbreviations are defined in the Specification and are used throughout the Specification and in the literature. For example, GLA is defined as γ-linolenic acid on page 8, line 22, DGLA is defined as dihomogammalinolenic acid on page 5 line 2, SA is defined as stearidonic acid on page 7, line 3, and EPA is defined as eicosapentaenoic acid on page 8, line 25. One of skill in the art, in light of the Specification would understand the meaning

of these commonly used names for the claimed unsaturated fatty acids and their use is thus not indefinite. Applicant respectfully requests withdrawal of this rejection.

The '285 patent neither teaches nor suggests the claimed invention.

The Action has rejected claims 1, 3, 5, 16-17 and 19-22 under §102(b) as anticipated by US Patent 5,223,285 ('285) and rejects claims 2, 4, 6-15, 18, 23-46, and 49-51 under §103(a) as obvious over '285. Applicant respectfully traverses the rejections.

The '285 patent appears to describe only a specific formulation for use as a medical nutrition product in patients with lung disease. What is described in the '285 patent is a complete system of nutrition for seriously ill patients that includes high fat content and low carbohydrate content. The contents of the lipid blends described in '285 are shown in Table 2 in which Blend C includes canola oil (31.8%) as well as medium chain tryglycerides (25%) and soy lecithin. Therefore, less than half the lipid blend is borage and fish oils.

This is in contrast to the present claims, in which the fatty acid portion of the compositions consist of specific oils designed to be effective in treatment of inflammatory disorders without increasing serum arachidonic acid levels. Although there is an overlap in the nutritional systems of the '285 reference and the claimed compositions, the claims must be looked at as a whole.

The present claims are drawn to compositions with a specific fatty acid portion which is neither taught nor suggested by the '285 patent. The claimed ingredients are chosen for a specific purpose, for example, as described in the first paragraph of page 6. As described in the Specification, the claimed formulations are designed so that GLA has its desired activity of suppressing inflammation in immune cells such as neutrophils, which do not possess Δ^5 desaturase activity and thus do not produce arachidonic acid (AA) from GLA. The side effect of

this treatment, however, is an increase in serum AA because non-immune cells such as hepatocytes do convert GLA to AA. Thus, the Δ^5 desaturase inhibitor prevents or inhibits the production of AA in the serum. The serum AA has been shown to increase platelet formation and it is an important contribution of the present invention to help prevent this dangerous side effect.

Because of the specific effect sought by the inventor, the other fatty acids supplied as nutrients for patients with lung disease as described in the '285 patent are not desired or necessary in the claimed formulas, and the '285 patent thus does not anticipate nor suggest the claimed inventions. Based on the disclosure of the '285 patent, one of skill in the art would find no motivation to pick certain ingredients from a larger formula in order to arrive at the claimed invention.

In addition, the '285 patent teaches away from the claimed invention. At column 13, line 51, the patent states that the ratio of EPA and DHA to GLA should be no lower than 1:1 and up to as high as 10:1 more EPA and DHA than GLA. In other words, the '285 patent describe formulas in which EPA is present at higher concentration than GLA. By contrast, the present claims are drawn to compositions with ratios of EPA to GLA of 1:1 down to 0.5:1. Thus, where the '285 patent appears to require higher levels of EPA than GLA, the formulas of the present claims require more GLA than EPA (a preferred Δ^5 desaturase inhibitor). Because the '285 patent neither teaches nor suggests the subject matter of the claims, and, in fact, teaches away from the present claims, Applicant respectfully requests that all rejections over '285 be withdrawn.

If the Examiner has any questions or suggestions that would help the present application proceed more quickly to allowance, a telephone call to the undersigned is earnestly solicited.

Respectfully submitted,

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MARKED-UP COPY OF CLAIMS WITH AMENDMENTS

1. (Amended) A composition for diminishing symptoms of inflammatory disorders, said composition comprising an unsaturated fatty acid portion, wherein said unsaturated fatty acid portion consists of γ-linolenic acid [or dihomogammalinolenic acid], a Δ^5 desaturase inhibitor, and optionally a competitive inhibitor of arachidonic acid metabolism, wherein the composition provides a ratio of γ-linolenic acid to Δ^5 desaturase inhibitor of from about 1:1 to about 2:1.

2. (Amended) The composition of claim 1, wherein the γ-linolenic acid [or dihomogammalinolenic acid], the Δ^5 desaturase inhibitor, and the competitive inhibitor are from around 80% to about 95% pure unsaturated fatty acids.

19. (Amended) A milk based drink for treatment of inflammatory disorders comprising an unsaturated fatty acid portion, wherein said unsaturated fatty acid portion consists of γ-linolenic acid, a Δ^5 desaturase inhibitor, and stearidonic acid, wherein the composition provides a ratio of γ-linolenic acid to Δ^5 desaturase inhibitor of from about 1:1 to about 2:1.

20. (Amended) A juice based drink for treatment of inflammatory disorders comprising an unsaturated fatty acid portion, wherein said unsaturated fatty acid portion consists of γ-linolenic acid and a Δ^5 desaturase inhibitor in a ratio of from about 1 to1 to about 2:1.

25. (Amended) A composition comprising a liquid comprising an unsaturated fatty acid portion, wherein the unsaturated fatty acid portion consists of 80-95% pure γ-linolenic acid, eicosapentaenoic acid, and stearidonic acid wherein the composition provides a ratio of γ-linolenic acid to Δ^5 desaturase inhibitor of from about 1 to1 to about 2:1.

40. (Amended) A dietary supplement in unit dosage form for delivery of a daily dose of said dietary supplement, which consists essentially of (i) at least 1 gram of GLA for increasing DGLA levels of a user, thereby inhibiting the metabolism of arachidonic acid, (ii) an effective amount of a Δ^5 desaturase inhibitor for inhibiting accumulation of arachidonic acid in the serum of said user and, optionally, (iii) an effective amount of a competitive inhibitor of arachidonic acid metabolism, wherein the supplement provides GLA and the Δ^5 desaturase inhibitor in a ratio of from about 1:1 to about 2:1.

49. (Amended) A dietary fatty acid supplement consisting essentially of purified water, ascorbyl palmitate, sorbic acid, sucrose, glycerin, xanthan gum, concentrated borage oil, concentrated marine oil, flavor and colorant, wherein the supplement provides GLA and the Δ^5 desaturase inhibitor in a ratio of from about 1:1 to about 2:1.